EXHIBIT C

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON
Master File No. 2:12-MD-02327 MDL 2327

DEPOSITION OF March 9, 2016
DONALD R. OSTERGARD, M.D.

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION
JOSEPH R. GOODWIN
U.S. DISTRICT JUDGE

THIS DOCUMENT RELATES TO THE FOLLOWING CASES IN WAVE 1 OF MDL 200:

HARRIET BEACH v. ETHICON, INC., ET AL.
Civil Action No. 2:12-cv-00476
SHARON BOGGS, ET AL. v. ETHICON, INC., ET AL.
Civil Action No. 2:12-cv-00368
ROBIN BRIDGES v. ETHICON, INC., ET AL.
Civil Action No. 2:12-cv-00651
ANGELA COLEMAN, ET AL. v. ETHICON, INC., ET AL.
Civil Action No. 2:12-cv-01267

AMANDA DELEON, ET AL. v. ETHICON, INC., ET AL.
Civil Action No. 2:12-cv-00358
DENNIS W. DIXON, ESTATE OF VIRGINIA DIXON, Deceased v. ETHICON, INC., ET AL.
Civil Action No. 2:12-cv-01081
DINA DESTEFANO-RASTON, ET AL. v. ETHICON, INC., ET AL.
Civil Action No. 2:12-cv-01299
PAULA FISK v. ETHICON, INC., ET AL.
Civil Action No. 2:12-cv-00848

JACKIE FRYE v. ETHICON, INC., ET AL.
Civil Action No. 2:12-cv-1004
TERESA GEORGILAKIS, ET AL. v. ETHICON, ET AL.
Civil Action No. 2:12-cv-00829

ROSE GOMEZ, ET AL. v. ETHICON, ET AL.
Civil Action No. 2:12-cv-00344

LOUISE GRABOWSKI v. ETHICON, INC., ET AL.
Civil Action No. 2:12-cv-00683

PAMELA GRAY-WHEELER v. ETHICON, INC., ET AL.
Civil Action No. 2:12-cv-00455
DAWNA HANKINS v. ETHICON, INC., ET AL.
Civil Action No. 2:12-cv-00369

JEANIE HOLMES, ET AL. v. ETHICON, INC., ET AL.
Civil Action No. 2:12-cv-01206
NANCY HOOPER, ET AL. v. ETHICON, INC., ET AL.
Civil Action No. 2:12-cv-00493

WILMA JOHNSON v. ETHICON, INC., ET AL.
Civil Action No. 2:12-cv-00809
BEVERLY KIVEL v. ETHICON, INC., ET AL.
Civil Action No. 2:12-cv-00591

PAUL KRIZ, ET AL. v. ETHICON, INC., ET AL.
Civil Action No. 2:12-cv-00938
DEBORAH LOZANO, ET AL. v. ETHICON, INC., ET AL.
Civil Action No. 2:12-cv-00347

BARBARA MASSICOT v. ETHICON, INC., ET AL.
Civil Action No. 2:12-cv-00856
EDITH NOLAN v ETHICON, INC., ET AL.
Civil Action No. 2:12-cv-00864

NOEMI PADILLA v. ETHICON, INC., ET AL.
Civil Action No. 2:12-cv-0567
STACEY PANGBORN v. ETHICON, INC., ET AL.
Civil Action No. 2:12-cv-01198

MIRANDA PATTERSON v. ETHICON, INC., ET AL.
Civil Action No. 2:12-cv-00481
JENNIFER REYES, ET AL. v. ETHICON, INC., ET AL.
Civil Action No. 2:12-cv-00939

JENNIFER SIKES, ET AL. v. ETHICON, INC., ET AL.
Civil Action No. 2:12-cv-00501

CARRIE SMITH v. ETHICON, INC., ET AL.
Civil Action No. 2:12-cv-00258

JANET SMITH, ET AL. v. ETHICON, INC., ET AL.
Civil Action No. 2:12-cv-00861
MARGARET STUBBLEFIELD v. ETHICON, INC., ET AL.
Civil Action No. 2:12-cv-00842

MARY LEE SWEENEY, ET AL. v. ETHICON, INC., ET AL.
Civil Action No. 2:12-cv-00807
KRYSTAL TEASLEY v. ETHICON, INC., ET AL.
Civil Action No. 2:12-cv-00500

SUSAN THAMAN v. ETHICON, INC., ET AL.
Civil Action No. 2:12-cv-00279
PATRICIA TYLER v. ETHICON, INC., ET AL.
Civil Action No. 2:12-cv-00469

CATHY WARLICK, ET AL. v. ETHICON, INC., ET AL.
Civil Action No. 2:12-cv-00276

The deposition of DONALD R. OSTERGARD, M.D., taken before Leeann Keenan, a Registered Merit Reporter, Certified Realtime Reporter, and a Notary Public in and for the County of Summit and the State of Colorado, at 7171 West Alaska Drive, Lakewood, Colorado, on Wednesday, March 9, 2016, at the hour of 9:01 a.m., pursuant to Notice.

APPEARANCES:

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P R O C E E D I N G S

(Witness duly sworn.)

DONALD R. OSTERGARD, M.D.,

having been first duly sworn, was examined and testified as follows:

EXAMINATION

BY MR. SNELL:

Q. Good morning, Doctor.

A. Good morning, sir.

Q. We met briefly off the record. My name is Burt Snell. I'm from the law firm Butler Snow, and I represent Ethicon and Johnson & Johnson in this litigation.

I have a head cold, as I told you. So if you cannot understand my questions or if you need me to repeat something, please just tell me and I'll do my best. I'm going to try to drink a lot of water and coffee --

A. Yeah.

Q. -- to keep us on track.

Can you state your full name and your current address, please.

A. Donald R. Ostergard. The only address I have is a home address, and I'd just as soon not have that on the record.

Q. That's fine. What city do you live in?
A. I live in Salida, S-A-L-I-D-A, Colorado.
Q. Colorado, okay.
A. I do have an office address in Torrance, California at the Harbor UCLA Medical Center.
Q. Are you still affiliated with the Harbor UCLA Medical Center?
A. I am professor in residence there, yes.
Q. What does "professor in residence" mean? That's a term I've never heard before.
A. Okay. It basically means that someone else is paying my salary. The university or the county are not paying a salary. So it's almost like a volunteer faculty.
Q. Okay. And how long have you held that position?
A. It's been, I think, a couple years at this point, approximately.
Q. Do you no longer treat patients?
A. I do not have a practice.
Q. Okay. When's the last time you treated a patient for pelvic organ prolapse?
A. Well, I assisted some of the fellows at Harbor UCLA a few years ago.
Q. Can you be more specific? When you say

"a few years ago," are you talking about 2010? 2013?

A. Let's see. Probably 2014, 2015. I'm sorry, I don't remember exactly.

(Exhibit No. 1 was marked.)

Q. I've marked as Exhibit 1 a copy of the amended notice of deposition. It's similar to the prior notice, except it just has more names. I saw, when I looked at the original notice, you had been disclosed as a general expert in some cases, and they did not have that on there.

So that's the purpose of the amended notice, and also to indicate that we're here taking your deposition regarding your general expert report today, as opposed to the case specific depositions that, as I understand it, will be later.

A. That's correct.

MS. THOMPSON: And just for the record, we filed objections to the notice.

MR. SNELL: Okay.

MS. THOMPSON: Hopefully you are aware of that.

MR. SNELL: I did see -- I have not been able to look it up, but I did see it on my phone that objections were filed.

Q. Can you tell me what, if anything, did you do to prepare for today's deposition, Doctor?

A. I reviewed lots of records, depositions, and the report pretty much outlines what I reviewed.

Q. When you say reviewed records, are you speaking to medical records or some other type of document?

A. The Ethicon records primarily. Of course medical literature as well. That's all outlined in the report.

Q. Fair to say, did you go back and re-review every piece of literature or document or deposition that you referenced in the body of your report?

A. Not every one, no.

Q. Any particular topic you refreshed yourself on in preparation for the deposition?

A. Mostly regarding Gynemesh.

Q. And how much time did you spend in preparation for today's deposition?

A. Since the --

MS. THOMPSON: Object to form.

A. Since the report was filed, do you mean?

Q. Well, how about we do it like that. Let's back up.

we did use Gynemesh after that.

Q. What was the reason or reasons why you abandoned Gore-Tex?

A. Because of the complications we were having with it.

Q. Meaning erosion?

A. Erosion was the main one, yes.

Q. Sinus tract formation?

A. What formation?

Q. Do you have sinus tract formation with Gore-Tex?

A. Sinus tract. I would have to go back and look at our papers to see if that happened. I don't recall.

Q. And the Gore-Tex we're talking about is Gore-Tex mesh, right?

A. Yes, not Gore-Tex clothing.

Q. Or the Gore-Tex sutures that I know you've used over your career, true?

A. Yes.

Q. Okay. And the Gore-Tex mesh is a microporous mesh, true?

A. Yes, incredibly microporous.

Q. It's essentially like the Gore-Tex winter wear jackets you would have, true?

A. Right. It's impermeable.
Q. Right. What is the pore size of the Gore-Tex mesh?
A. I really don't know, but I don't think you could call them pores.
Q. It's more like a sheet?
A. It's a sheet, yes.
Q. You understand the pore size of Gynemesh PS to be about 2 1/2 millimeters?
MS. THOMPSON: Object to form.
A. Well, that's what's been reported, but that totally ignores all the other pores, the ones that go down to maybe a third of a micron. So there's not a good idea that Ethicon actually acknowledged that, to put a number on pore size, because there are multiple pores involved.
Q. You understand in your field, by doctors who look at and characterize meshes, they tend to report the largest pore size for a mesh, true?
A. That's true.
MS. THOMPSON: Object to form.
A. That's not a correct characterization of the mesh.
Q. And if there is a pore that's 2 1/2 millimeters, yet there's a strand of the filament

running through the middle, what you're saying is then that makes the pore not 2 1/2, but 1.25 and 1.25, hypothetically?

MS. THOMPSON: Object to form.

Q. I'm not locking you into those numbers. I'm just trying to understand what you're saying.

A. Well, if you look at the diagram of a pore --

Q. All right.

A. -- or of the mesh, let's say, you will see that there are multiple pores, and some of them are considered interstices. In other words, so small that a macrophage or a white blood cell can't get in, but the bacteria can. And that's one of the big disadvantages of the use of this form of material.

Q. When you used Gynemesh PS, did you notice any type of very high infection rate with it?

A. No, because we put it in sterilely.

Q. Now, you've heard of the Amid classification, obviously?

A. Yes, for what it's worth.

Q. Biologically the cells that are involved in the laying down of collagen, but also the cells that are responsible for attempting to handle

bacteria, those are all cells that are so small you can only see them on a microscope, true?

A. Those cells require a microscope for visualization, yes.

Q. All right. And you mentioned a macrophage. You are aware that a macrophage can traverse around a mesh filament, true?

MS. THOMPSON: Object to form.

A. Yes, that has been published.

Q. You are --

A. They can change their shape to some degree to do that.

Q. Exactly. You are aware that macrophages can change their shape and emit, some people have called it, like an arm, pseudopod?

A. Pseudopod, that's right.

Q. True. Such that if there was a bacteria in the interstices, the macrophage can come sit down on top of it and emit pseudopod filled with bacteria, true?

MS. THOMPSON: Object to form.

A. Assuming that bacterium had not encased itself in bacterial slime. If it does that, then it cannot do as you described.

Q. However, if it does that and the

sacrocolpopexy?

A. More often than not, I would just use the sacrocolpopexy.

Q. Okay. You've read literature that indicates that there is a relation between the apical part of the vagina as well as the anterior and posterior walls?

A. I don't understand your question.

Q. Are you generally familiar with literature that indicates, going back to publications by John DeLancey, that if there's a multicompartment defect, including the apex, the most important part to try to put back anatomically is the apex because it has an effect on the anterior and posterior walls if not treated?

A. Typically that's true, yes.

Q. And is that something you subscribe to?

A. Yes.

Q. Did you use Gynemesh PS transvaginally?

A. No.

Q. Did you use any meshes transvaginally?

A. The only meshes that I have used are Gore-Tex.

Q. Gore-Tex.

A. And polypropylene mesh for suburethral

slings.

Q. You never freehand cut the Gynemesh or Gynemesh PS and sutured in place for prolapse repair?

A. No.

Q. The polypropylene mesh you used for stress incontinence was the TVT, true?

A. No.

Q. Do you recall giving deposition testimony that you've used the TVT, but you alter the approach by making a wider dissection near the urethra, and you don't pass the trocars fully from the top all the way down to the bottom. You stop when you hit your finger. Do you not recall giving that testimony?

A. I did that, but not with the TVT.

Q. Have you ever used the TVT?

A. No.

Q. What polypropylene mesh slings have you used for stress incontinence?

A. The SPARC. I've used the components of the SPARC, but not as directed by AMS. I did it the way you described, basically.

Q. Okay. And did you find that use of SPARC to be safe and effective transvaginally?

A. In the absence of data, I'm not sure I can answer that question because I did not follow-up these patients to the point where I can make a definitive statement to that regard.

Q. Per your general recollection, do you have any reason to believe that your patients did not do well that you treated with SPARC?

A. In the absence of data, I suppose. But if I don't have any objective information to verify that, I really can't tell you.

Q. Are you aware that the pore size of TVT is larger than the pore size of SPARC?

A. I don't recall --

MS. THOMPSON: Object to form.

A. -- specifically.

Q. Are you aware that -- you know there's a Cochrane review on slings, just like the Cochrane review you brought about prolapse mesh?

A. Yes, there's Cochrane reviews on virtually everything.

Q. I think the lead author of that sling Cochrane review was Ogah, O-G-A-H. Are you generally familiar with that Cochrane review?

A. Yes, generally, but I would have to see it again at this point to make any comments on it

definitively.

Q. I'm going to ask you to do this: Do you have a general recollection that when top-to-bottom polypropylene slings, like SPARC, are compared to bottom-to-top, like TVT, the slings like SPARC had lower efficacy and higher exposure rates?

A. Well, since I didn't do it as a SPARC procedure, we're not talking about what I did in comparison to the TVT.

Q. But you still left a polypropylene midurethral sling implanted transvaginally in the patients, true?

A. That is true.

Q. What was your exposure rate with the SPARC, if you track that at all?

A. I did not track anything regarding these patients.

Q. Okay. When did you learn to do the sacrocolpopexy?

A. When?

Q. Yes. Is that something you learned in your residency or once you got out in practice?

A. I'm not really sure. I certainly used it in my practice, but I don't recall specifically being taught it in residency.

Q. Okay. Sacrocolpopexy has been out since the 1960s, true?
A. Yes, I would assume.
Q. When did you begin doing sacrocolpopexies? You can just tell me the decade.
A. Probably in the '80s.
Q. Okay. Did you find that there was adequate tissue integration with the Gynemesh PS that you placed?
A. I never evaluated the patient for tissue integration.
Q. Was there adequate suspension of the prolapsed organs, in your opinion, with the Gynemesh PS you placed?
A. Yes.
Q. What was your rate of exposure with the Gynemesh PS, if you tracked it at all?
A. I did not track them, so I cannot tell you.
Q. For the Gore-Tex mesh you used, did you track those complication rates?
A. Gore-Tex for?
Q. For prolapse repair.
A. For prolapse repair. We tracked them for suburethral slings. That was all.

Q. Okay. Have you ever had to go in and remove a Gynemesh PS mesh that got infected?

A. No.

MS. THOMPSON: Object to the form.

Q. Can you give me your best estimate of how many Gynemesh PS meshes you placed in your career?

A. You want a guess? That's what it's going to be.

Q. I don't want a guess. I want your best estimate. So if you say, you know, on average I did, you know, 20 or 30 sacrocolpopexies a year, the majority of those were Gynemesh PS. I'm just looking for your best estimate.

A. Yeah.

Q. I'm not going to hold you to a number. I will promise you that. I'm asking you, so let me just make the record completely clear, can you give me your best estimate as to the number of Gynemesh PS meshes you placed over your career?

MS. THOMPSON: Object to form.

A. I'm not even sure I can even characterize it as an estimate, but probably in the range of 50 to 100.

Q. Okay. I think earlier you mentioned you worked with training residents at UCLA Harbor View a

couple years back?
A. I primarily was training the fellows.
Q. The fellows, sorry.
Were those fellows using the TVT sling made by Ethicon?
A. I do not believe so.
Q. They were using SPARC?
A. No, sir.
Q. What sling were they using, if you know?
A. It was the, I believe the Boston Scientific Advantage sling.
Q. That's a polypropylene sling?
A. Yes, sir.
Q. When did you begin using the SPARC sling?
MS. THOMPSON: Object to form.
A. I know I used it before I closed my practice in Long Beach.
THE WITNESS: I'm sorry, I'm not speaking up. My voice, same cold he has (indicating).
A. The -- again, as best estimate, 2010.
Q. During your residency, can you tell me what were the prolapse repairs you were trained on, besides the anterior and posterior colporrhaphy?
A. The procedures you mentioned, plus the

plication of the uterosacral ligaments as part of a prolapse repair for the apex of the vagina, primarily posthysterectomy.

Q. I'm familiar with the term "uterosacral ligament suspension." Is that the same thing as what you just referenced as a uterosacral plication, or are they different?

A. I think you probably would say they were different, since the suspension you're talking about is usually done at the level of the spine, approximately. And sutures are placed there and then into the vagina.

We're talking about a -- very much a lower plication of the uterosacral ligaments. It's called a McCall culdoplasty.

Q. Okay. I've heard of that. So you're going more lateral as opposed to high up?

A. No, we're not going lateral. We're following the uterosacral ligaments and placing sutures in it.

Q. Okay.

A. The uterosacral ligament that we've just detached from the uterus.

Q. Okay.

A. And plicating that and obliterating the

Q. For purposes of my question --
A. As --
Q. For purposes of my question, I'm not focused on him. I want to go back to my question.
So are there any Level 1 randomized control trials that report degradation with Gynemesh PS?
MS. THOMPSON: Object to form.
A. There's no randomized control trials. I mean, no one has ever taken 100 patients with the mesh there, extracted that mesh from those 100 patients and looked at it. That would be something no Human Subjects Committee would approve, so it's not possible to do such a study. So to answer your question, there is no Level 1 evidence --
Q. Okay.
A. -- from such a study designed that way.
Q. So the surface cracking that you mentioned, a study has not been done yet which shows whether that is a finding in patients who have good prolapse repair and no complications as compared to patients who have complications, true?
A. Well, the mesh is --
MS. THOMPSON: Object to form.
A. -- available for analysis. It comes from

patients who have a complication severe enough to remove that mesh. It couldn't be done otherwise. No Human Subjects Committee would approve that.

Q. What I'm saying is the surface cracking that's been reported by some folks, that could be a normal finding in asymptomatic patients with good cure of their prolapse and no complications because the study -- a study hasn't been done with that type of control to show whether this cracking is actually causal of any of the complications, true?

MS. THOMPSON: Object to form.

A. At this point in time, we cannot specifically relate degradation to complications in patients. The only time we are able to see this degradation, and I think this was mentioned in one of Ethicon's patients -- oh, it is attached to one of the expert reports, or is mentioned that on removal of the mesh, it fell apart. It fell apart, so all the mesh could not be taken out.

And this has been my experience as well. The mesh frequently does that. You can't get it all out. And even Ethicon has likened this to rebar in concrete. You can't get the rebar out. And now these patients have remaining polypropylene mesh in them, which can at some time in the future

cause problems for them.

And I hate to bring up the cancer issue, but there are now two neoplasms that have been described with polypropylene mesh. And they'll actually be published formally next month, and so these patients have this knowledge if that work gets caught in the media attention and the media says that it causes cancer. Well, there's no proof it causes cancer. It's just an association at this point. But these patients then are going to be clamoring to have their mesh taken out so they don't have to worry about the possibility of cancer sometime in the future, and I think this is a major issue.

Q. So I'm going to respectfully move to strike some of your answer that went beyond my question.

MR. SNELL: Can you read back his answer where he says, "At this point we cannot relate degradation to complications." I think something like that.

(Record read as follows:
at this point in time, we cannot specifically relate degradation to complications in patients.

The only time we are able to see this degradation, and I think this was mentioned in one of Ethicon's patients -- oh, it is attached to one of the expert reports, or is mentioned that on removal of the mesh, it fell apart. It fell apart, so all the mesh could not be taken out.)

MR. SNELL: So strike everything after that.

Q. The reason I'm doing that, I didn't see in your expert report that you issued opinions about cancer.

A. No, these hadn't been published at the time that that report was written.

Q. No, I'm talking about --

A. But they're on my reliance materials.

Q. Well, I didn't see that you issued opinions that you plan to testify at trial that Gynemesh PS causes cancer or sarcoma.

A. I would never testify that it causes cancer. All I could testify to is it has been found in association with cancer.

Q. At a break I'm going to look at your

report because if it's not in the report, then I'm going to respectfully move to strike.

But if you disclosed in here that you plan to talk about cancer or sarcoma, then we'll get into that a little bit.

A. I don't think it's in the report.

Q. Okay.

THE WITNESS: Can we take a real quick break?

MR. SNELL: Absolutely.

THE WITNESS: Thank you.

(Break from 11:33 a.m. to 11:40 a.m.)

(Exhibit No. 14 was marked.)

BY MR. SNELL:

Q. I've handed you Exhibit 14, Doctor, which is a paper by Withagen and other authors concerning sexual functioning after Prolift. Do you see that?

A. Yes, I do.

Q. Is this a study you're familiar with?

A. It's an abstract I'm familiar with, yes.

Q. So preoperatively in these patients who were treated Prolift, it was reported that their prolapse significantly interfered with their sexual function, correct?

Q. What types of surgeries?
A. Pardon me?
Q. What types of surgeries?
A. Either abdominal or vaginal.
Q. In a hysterectomy, or...
A. I don't remember.
Q. Let me just ask you: So what surgical procedures did you use Prolene sutures in?
A. I don't remember specifically.
Q. Okay.
A. It was one of the choices we had.
Q. For your prolapse surgeries, do you have -- when you use sutures, do you have a personal preference?
A. Yes.
Q. What was that?
A. Delayed absorbable sutures.
Q. Did you use delayed absorbable sutures -- let me back up. I'm not sure if I asked you this question.

Did you do sacrospinous ligament fixation for prolapse?
A. Yes.
Q. Okay. And you also did uterosacral ligament suspension for prolapse as well, true?

A. From the standpoint of a McCall culdoplasty, yes.

Q. Did you use permanent or delayed absorbable sutures for those procedures?

A. Those are permanent sutures.

Q. What prolapse surgeries did you prefer the delayed absorbable sutures for?

A. Typically colporrhaphies.

Q. When you did the sacrospinous ligament fixation, what suture did you use?

A. I think we used the braided polyester suture probably most commonly, Ethibond.

Q. Would you have used that same braided polyester permanent suture for the uterosacral ligament suspensions as well?

A. Yes, likely.

Q. You don't consider yourself a biomaterials expert?

A. A biomaterials expert, no.

Q. There's been reports in the literature that the surface cracking seen on some of the explants could be due to a biologic proteinaceous material. Are you familiar with that?

A. Yes.

MS. THOMPSON: Object to form.

A. I've seen some people postulate that.
Q. Have you done any testing to evaluate that postulation?
MS. THOMPSON: Object to form.
A. I've done SEM of polypropylene, and significant biofilm was not apparent.
Q. That wasn't the Gynemesh PS, though, right?
A. It was not.
Q. What was this done in connection with? What type of polypropylene?
A. I'm sorry?
Q. That was my fault.
A. No, my hearing aid.
Q. The polypropylene you did look at, what was that polypropylene?
A. Which products?
Q. (Nodding head.)
A. Uphold.
Q. How many specimens did you evaluate of that Uphold?
A. How many specimens?
Q. Yes.
A. There was just one specimen, one specimen taken out of the patient.

Q. Okay. You didn't have a control group that you used and compared it to?

MS. THOMPSON: Object to form.

A. We did look at pristine sutures, as I recall -- excuse me, pristine mesh as well.

Q. But not mesh that had been in the human body?

A. Mesh that's not been in the human body, correct.

Q. So my question is for this one specimen, you didn't have a control of mesh that had been in the human body to compare the two, true?

A. No, there was only one specimen.

Q. Okay. Do you believe that you're an expert in polymer chemistry?

A. No.

Q. Have you read in the literature that there can be a cross-linking when pathologists use formalin for preservation?

MS. THOMPSON: Object to form.

A. Excuse me, there can be what?

Q. A cross-linking of proteins when pathologists use formalin for preservation of specimen?

MS. THOMPSON: Objection.

Q. Have you read that, or not?
A. It seems like I have, yes.
Q. Do you consider yourself an expert in that?
A. No.
Q. I take it you don't consider yourself to be an expert in pathology either?
A. I'm not --
MS. THOMPSON: Object to form.
A. -- a trained pathologist, if that's what you mean.
Q. Would you agree that the high rates of anatomic efficacy seen with Prolift is inconsistent with a theory of degradation?
MS. THOMPSON: Object to form.
A. Inconsistent with what?
Q. A theory of degradation.
A. No, because mesh can degrade and leave scarification behind. And so you'll still have the same effect, irregardless of the fact that degradation has occurred.
Q. Has that been tested, to your knowledge, as to whether the sustained anatomic efficacy is because of scarring or the mesh?
MS. THOMPSON: Object to form.

A. Because of what?
Q. Because of the scarring or because of the mesh providing support?
A. That's a study that's almost impossible to do.
Q. You haven't seen anyone try to do that study in the literature?
A. No, I haven't.
MR. SNELL: Let's take a break. Let me organize myself.
THE WITNESS: Okay.
(Whereupon, a lunch break was had from 12:03 p.m. to 1:08 p.m.)
EXAMINATION (CONTINUED)
BY MR. SNELL:
Q. In your expert report, Doctor, at pages 3 and 4 you list some other meshes; Polyform, POP Mesh, Pelvitex, and TiMesh. Do you see that?
A. I think I did list them. I don't see them right now.
Q. (Indicating).
A. Oh, okay.
Q. And then if you flip the page (indicating).
A. Pelvitex, TiMesh.

Q. My question to you, Doctor, is have any of those meshes been studied in patients with prolapse in randomized control trials?

A. I don't know.

Q. Have you seen any studies in women who have undergone implantation of those meshes for the treatment of pelvic organ prolapse?

A. Not that I recall.

Q. We saw that there are various studies with Gynemesh PS, some of them even going out to five or seven years, correct?

A. Yes.

Q. Would you consider five-year studies to be long-term studies?

A. Yes.

Q. As far as you're aware, those other meshes, there are no long-term studies in the treatment of pelvic organ prolapse for those, true?

A. I don't believe so.

Q. You have not seen any prospective studies that show that Gynemesh PS has a statistically significant increased risk of any complication compared to those other meshes; Polyform, POP Mesh, Pelvitex and TiMesh, true?

A. I'm not aware of any comparative studies

with them.

Q. We've talked about Gynemesh PS, and it has demonstrated anatomic superiority to native tissue, according to Level 1 randomized control trials, true?

MS. THOMPSON: Object to form.

A. Yes, in those individual studies.

Q. For these other meshes you reference -- Polyform, POP Mesh, Pelvitex, TiMesh -- there is no similar data that you're aware of demonstrating that benefit, true?

A. That is correct.

MS. THOMPSON: Object to form.

Q. Have you seen any studies reporting rates of a mesh exposure or dyspareunia with those other meshes?

A. No, I have not.

Q. It is not your opinion that those are suitable alternative meshes to Gynemesh PS, true?

A. No, those were just ones that were compared to these particular studies.

Q. And you have seen no demonstrable benefit to those meshes compared to Gynemesh PS in women, true?

A. I don't think there are any publications

on these other meshes.

Q. TiMesh, do you even know if that's been FDA cleared in this country?

A. I haven't -- I don't have information one way or the other.

Q. Have you looked at the regulatory status of any of those alternative prolapse meshes?

A. I don't know that they are alternative prolapse meshes. They were just exemplar just to compare Gynemesh to.

Q. Let me rephrase then. Thank you for that correction.

For those exemplar other meshes, did you investigate the regulatory status of them for the treatment of pelvic organ prolapse in women in this country?

A. No, I did not.

Q. There are no studies in patients that show that having a mesh with a larger pore size than Gynemesh PS leads to a statistically significant reduction in complications, true?

MS. THOMPSON: Object to form.

A. I think that's correct.

Q. You have not seen any randomized control trials that demonstrate that non-mesh native tissue

has a statistically significant better anatomic benefit compared to Prolift or Gynemesh PS, true?

MS. THOMPSON: Object to form.

A. I'm wondering about one study, but without seeing it I can't comment.

Q. As you sit here today, you're not aware of any native tissue studies that show a statistically significant benefit in anatomic correction of prolapse compared to Gynemesh PS and Prolift, true?

A. As I'm sitting here today. That doesn't mean it doesn't exist.

Q. There are no randomized control trials that compare native tissue repairs to Gynemesh PS or Prolift that show that the native tissue repair has statistically significant better subjective benefits for prolapse symptoms, true?

MS. THOMPSON: Object to form.

A. I think that the studies that have been done have shown equal effectiveness in that regard, as far as the patient is concerned.

Q. So the answer then would be you're not aware of any studies showing native tissue having a statistically significant benefit over and above Prolift and Gynemesh PS for subjective patient

comparisons.

Q. Is it correct then that you do not hold an opinion as to the adequacy of the Prolift IFU?

MS. THOMPSON: Object to form.

A. That is not correct.

Q. Are you basing -- well, do you -- do you have an opinion then that the Prolift IFU is inadequate in some form or fashion?

A. Yes. It doesn't warn against degradation, for one thing.

Q. So is there any regulatory standard that you have considered and factored in in that opinion?

A. A regulatory standard for devising an IFU?

Q. Yes.

A. I'm not sure if one exists.

Q. Is it your opinion that the IFU should -- strike that.

Is it your opinion that the Prolift IFU should say that the mesh can degrade?

A. Yes, absolutely.

Q. And that is based on your personal opinion, true?

MS. THOMPSON: Object to form.

A. That is based on my opinion and my review

of the information regarding degradation, when Ethicon knew about it and physicians should have been told. It's a very important factor in their decision whether or not to use a product.

Q. Have you done any study of physicians' attitudes as to whether surface degradation would lead them to not use Prolift?

MS. THOMPSON: Object to form.

A. I have not done any such studies.

Q. Hypothetically, if degradation were to occur, the clinical manifestation of that, if any, would be variable, true?

MS. THOMPSON: Object to form.

A. Well, since we don't know what the manifestations are, it's very difficult to answer that question.

Q. Fair enough.

When did you first look at the Prolift IFU?

A. When did I first look at it?

Q. Yes.

A. I can't tell you the exact date.

Q. Okay. You have looked at it, though?

A. I have looked at it, yes.

Q. Okay.

MR. SNELL: Let's mark it.

(Exhibit No. 16 was marked.)

Q. 16.

A. Thank you.

MS. THOMPSON: Thank you.

Q. We've talked about a whole lot of different complications that can occur with the different prolapse surgeries.

Mesh exposure/erosion, that's a unique risk with mesh, correct?

A. Quite unique.

Q. Conversely, you can have suture erosions with non-mesh repair, true?

A. Which are typically of no consequence, whereas the erosions that you're speaking of do have consequences.

Q. There can be contraction with Prolift, correct?

A. Yes.

Q. And there's also tissue contraction with native tissue, true?

MS. THOMPSON: Object to form.

A. Depends on how the surgery is done. It can be avoided, generally.

Q. Well, if there's scarring, there's going

to be tissue contraction. I thought we agreed to that?

A. I'm sorry, I'm not hearing.

MS. THOMPSON: Object to form. Misstates his testimony.

Q. If there's scarring, there is going to be tissue contraction?

A. Yes. But the type of contraction you're talking about is not something that generally bothers a patient.

Q. Well, what we've discussed is that with contraction, the potential outcome of that is pain, that you identified, right?

A. Not with --

MS. THOMPSON: Object to form.

A. -- native tissue repairs, no.

Q. Have you -- let me back up.

Regardless of what the contraction leads to, there is no data showing a significantly higher rate of those complications with Prolift compared to non-mesh repair --

MS. THOMPSON: Object to form.

Q. -- true?

A. I think we've been over this already.

Q. I'm just trying to make sure that we're

not changing now.

A. I'm not going to change.

Q. So let's look at the Prolift IFU. Actually, on the first page you see it says, "Training on the use of Prolift is recommended and available."

A. That's too bad it doesn't say it's required.

Q. Well, are you --

A. That's a defect in this.

Q. Are you aware of any regulatory standard that requires a surgeon to undergo specific training of a device before he or she can use that device?

MS. THOMPSON: Object to form.

A. Physicians typically undergo training for any type of surgery they do before they do that surgery. Why should mesh be an exception?

Q. So if a surgeon wants to use a specific medical device, are you aware of any regulatory standard or requirement that they be trained on that particular device?

MS. THOMPSON: Object to form.

A. I am not aware of any regulatory standard, but it does not mean that Ethicon or any other company can't go beyond and make sure that the

physicians that are going to use their devices are adequately trained to put the devices in safely.

Q. Well, you do know that Ethicon offered training, true?

A. Yes, they offer it.

Q. You are aware that AUGS has come out with guidelines for credentialing surgeons in doing prolapse surgeries, true?

A. Yes, I've seen that.

Q. Part of what they recommend is that, hey, surgeons go do training, true?

A. Absolutely.

Q. Are you saying it's a bad thing that Ethicon offered professional education training for Prolift?

A. Definitely not.

MS. THOMPSON: Object to form.

A. The bad thing is that it wasn't required, since this was for something that was brand new to the gynecologic and urological communities. They didn't know anything about how to place these meshes, and the insertion technique for the Prolift is extremely, extremely complicated.

Q. You didn't undergo any specific industry training when you decided to start using mesh to

treat sacrocolpopexies, true?

A. I had done the procedure using other things before.

Q. You felt competent --

A. So it's simply a matter of substituting something else for what I had been doing.

Q. You felt competent in your ability to carry out that mesh procedure safely, without going to Ethicon or some other manufacturer and saying, "Can you train me on this," true?

A. Since it's the same procedure that I've done for many years before, I don't see any reason to do that. This is brand new.

Q. Well, what Prolift --

A. If I was going to start doing these, I would want to know everything about it and I would definitely go to training to see what is recommended. No question.

Q. And your understanding is that with Prolift, the anterior Prolift, the mesh goes out to the arcus tendineus, true?

A. Yes.

Q. And that's a route of prolapse repair that had been in existence before Prolift, true?

A. Yeah, but --

A. I can't point to any specific thing at this point.

Q. So on a scale of 1 to 10, with 1 being just piss-poor shoddy and 10 being perfect, where would you put Ethicon's IFU and professional education program?

MS. THOMPSON: Object to form.

A. The big problem is the omission of the things that I've already talked about. So I would have to say that this is a good attempt, but there are very important things that have been left out.

MR. SNELL: All right. Let's take a break and let me just wrap it up.

MS. THOMPSON: Sure. And then I'm probably going to need a little break between when you finish and redirect. Unless you just have a couple questions, then we can take the whole break at the same time.

MR. SNELL: I'll do whatever you want to do.

MS. THOMPSON: Oh, my gosh, you're so agreeable.

MR. SNELL: I am very accommodating.

(Break from 2:58 p.m. to 3:06 p.m.)

BY MR. SNELL:

Q. You had mentioned the cancer thing earlier. I'm just going to ask you a couple questions about that and see if we can't be done with it. Because I don't really think it was within the scope of your report, but you did raise it.

So as we sit here today, there are no studies in women that demonstrate that Gynemesh PS or Prolift causes cancer, true?

A. No causation has been established, only association.

Q. And the truth of the matter is an association has not been established because there have been no epidemiologic studies that show a statistically significant increased risk of any cancer or seroma formation in women, when adjusted for potential confounding factors, as compared to the population background, true?

A. Well, since there's only been one case reported, yes.

Q. Are you familiar with -- there's been a couple epidemiologic studies that have been published recently, looking at cancer rates in women treated with polypropylene midurethral slings?

A. Yes.

Q. I think the most recent one was a paper by a Dr. Linder. It was in the International Urogyne Journal just last month, a cohort of 2,474 women.

A. Yes.

Q. Is that a paper you've read?

A. Yes. The time period is too short, however, to make any conclusions.

Q. Well, what they found was that there was about a 2 percent rate of background cancer in those patients, true?

A. Something like that, yes.

Q. And there were only two cases out of the entire cohort where the cancer was diagnosed after sling implantation. Do you recall that?

A. But not associated with the sling.

Q. Correct. The rate was 0.08 percent.

A. It takes 20, 30 years for a carcinogenesis to be effective. So we haven't seen the last of this, I'm sure.

Q. But the fact of the matter is obviously vaginal bladder cancers, those are naturally occurring in the background, as one can see in that Linder paper, where 2 percent of the patients had a preexisting history of cancer, correct?

A. There are background rates of neoplasia, yes.

Q. And you have seen no reliable epidemiologic studies in women that show that the rate of cancer with the polypropylene mesh is statistically significantly higher than the background, when adjusted for other confounders, true?

A. There's been no such paper.

Q. And you would agree with authors who have written on this topic, that have stated in order to establish an association between polypropylene mesh and cancer one has to be -- it has to be demonstrated by more than mere case reports, true?

A. It has to be demonstrated by more than a mere case report? Is that what you said?

Q. More than mere case reports.

A. Well, the case report is the starting place to call people's attention to this may be possible.

Q. Right.

A. And one of the problems that I've noticed in reviewing cases, that when specimens are excised from a patient, frequently there's never histology to them. So they may be throwing away preneoplastic

or neoplastic conditions, and they don't even know it.

Q. They may be throwing away totally benign?

A. Absolutely. I sure hope so.

Q. And we don't know because we don't have those data, true?

A. They have not been examined histologically, so we don't know.

Q. I believe you made mention of toxins in your report. Are you aware of any studies in women that show that any toxins lead to significantly higher complication rates for Prolift or Gynemesh PS?

A. There are no studies in relation to polypropylene. We don't even know for sure what the toxins are. They haven't been measured, and we do not know if there is increase in adverse events because of it.

Q. Okay.

A. We have no way, no way to know at this point.

Q. Okay.

MR. SNELL: That's all the questions I think I have. I'll pass the witness.

MS. THOMPSON: Okay. Let me go ahead

and take a break.

MR. SNELL: Okay.

MS. THOMPSON: And then I'll be ready to go all the way through without having to stop. So break.

THE WITNESS: Okay.

(Break from 3:12 p.m. to 3:23 p.m.)

(Exhibit Nos. 21 through 46 were marked.)

EXAMINATION

BY MS. THOMPSON:

Q. Dr. Ostergard, did you review and critically assess all the literature that you found on Gynemesh and Prolift, regardless of whether it was favorable or unfavorable to your opinions?

A. Yes, I did.

Q. I want to go through just a few, not all, of the literature that counsel showed you earlier. But let's start with the Francis and Jeffcoate article from the Journal of Obstetrics and Gynecology. I don't remember the exhibit number, unfortunately. We're going to mess all these up for Leeann.

A. 1 or 2. It was actually 7. The staples

REPORTER'S CERTIFICATE

I, LEEANN L. KEENAN, Registered Merit Reporter and Certified Realtime Reporter within Colorado, appointed to take the deposition of DONALD R. OSTERGARD, M.D., do hereby certify that before the deposition he was duly sworn by me to testify to the truth; that the deposition was taken by me at 1801 California Street, Suite 5100, Denver, Colorado; then reduced to typewritten form herein; that the foregoing is a true transcript of the questions asked, testimony given and proceedings had.

I further certify that I am not related to any party herein or their Counsel, and have no interest in the result of this litigation.

In witness hereof I have hereunto set my hand this 28th day of March, 2016.

Leeann L. Keenan
Registered Merit Reporter
Certified Realtime Reporter
and Notary Public

LEEANN KEENAN NOTARY PUBLIC STATE OF COLORADO My Commission Expires 6/8/2016

My commission expires June 8, 2016